

ATTACHMENT 2

STATEMENT OF WORK

RFQ-RT-13-00032
STATEMENT OF WORK

A. Background Information

Potential neurotoxicity from airborne Manganese (Mn) exposure has been a community and risk assessment concern for more than a decade in Region 5 (e.g. OH, MI). The RARE program funded a 2009-2010 Mn health study in Marietta OH near a large industrial emitter of airborne Mn, led by San Francisco State University. Mt. Vernon OH, demographically similar to Marietta but without large industrial Mn emission sources, was used as the comparison community for Marietta. Initial Marietta-Mt. Vernon comparisons generally indicate a lack of major health effect differences between the two towns. In November 2011, San Francisco State University conducted a study using the same protocols, staff and measurement techniques in East Liverpool OH. Some of the highest chronic US residential Mn inhalation exposures are likely to have occurred in this area, with outdoor Mn concentrations up to 50-fold higher than the previous two Ohio towns.

The proposed comparisons of the results from the enrolled cohorts in these three communities are important in that either positive results (differences between East Liverpool and comparison communities) or negative results (little or no differences among communities) inform the issue of potential health effects of residential airborne Mn exposure, a recognized gap in Mn health effects literature. Therefore, either outcome can help inform the need for greater airborne Mn control. In addition, the present requirement addresses the USEPA Administrator's environmental justice priority. The poverty rate is higher in East Liverpool (25.2%) than in Marietta (16.9%), Mt. Vernon (15.6%), the State of Ohio (7.8%) or the U.S. (9.2%).

B. Purpose and Objectives

This study will evaluate whether long term (minimum 10 years) residential airborne Mn exposure can affect human health. The Contractor shall compare already available study data from adult residents of Marietta and Mt. Vernon with the results with those of East Liverpool for biomarkers (blood metals, toenails, hair), medical tests (symptoms; illnesses; Unified Parkinson's Disease Rating Scale evaluation), functional tests (mood; neuropsychological tests such as working memory and attention, verbal skills, motor dexterity/strength, visual tracking speed); and questionnaires (life style habits; work; dietary Mn). Key research questions include:

- Are blood and plasma Mn (controlled for Cd, Hg, and Pb exposure by measuring these metals in whole blood; controlled for Fe status and liver function by measuring plasma ferritin and the hepatic enzymes ALT and GGT, respectively) significantly elevated in East Liverpool adult residents vs. those in Marietta and Mt. Vernon? An additional novel diagnostic biomarker using toenails and hair shall be used to assess longer term Mn exposure (7-10 months).
- What differences in environmental and lifestyle factors may contribute to blood, hair, and toenail Mn levels in East Liverpool residents?
- Is Mn body burden associated with altered neurological and neuropsychological function, or medical symptoms and illnesses?
- Do health outcomes (e.g. neuropsychological test results) differ among the three towns?
- Can Mn exposure-effect relationships with health and illness be shown through use of an exposure index?

The November 2011 community based study was a high visibility research initiative within this Region. Several newspaper articles and television reports featuring San Francisco State University tracked the progress of the study during the field data collection portion of this project. The Region has since received enquiries from the media asking for updates and any findings. In order to address community concerns, the Contractor shall prepare and present the results of this study in a public meeting in East Liverpool, Ohio.

C. Specific Objectives/Milestones to be Performed by the Contractor

The Contractor shall send individualized reports to the East Liverpool, Ohio study participants; prepare and conduct a public meeting in East Liverpool to present and explain results of the study; measure the Mn content of hair samples and report the results to the EPA; analyze data; produce reports and manuscripts for this study. The Contractor shall abide by the requirements of the previously EPA approved Quality Assurance Project Plan (QAPP) for this study, developed under Contract EP-11-D-000424.

In the Base Year, the Contractor shall perform the following Tasks:

1. Send individualized reports to the East Liverpool, Ohio study participants (a total of 86 reports). The Contractor shall include their contact information as part of these reports and be prepared to answer questions from study participants. The Contractor shall prepare and conduct a public meeting in East Liverpool to present and explain results of the study, to date. The Contractor shall be responsible for finding and renting the meeting location. This location must be able to seat a minimum of 150 people. The Contractor, in conjunction with representatives from the State of Ohio, shall publicize the date, location and topic material for the public meeting. The Contractor's presentation materials will require EPA review and approval prior to the public meeting. The Contractor shall deliver a copy of their presentation materials and script to the EPA at least three weeks prior to the public meeting. The EPA will review the presentation and obtain clearance within 14 calendar days of receipt. This review is required under an Office of Research and Development (ORD) internal policy which can be found at:

<http://dcordhqapps1.epa.gov:9876/ORMA/ActXMIT.nsf/de624e5eddab032b85256cdf00594b3b/961ddad20fade56685257a60005be648?OpenDocument>

In brief, "Clearance is the process of obtaining approvals by the appropriate ORD managers prior to releasing a scientific or technical work product." All journal articles, reports and presentations which describe EPA / ORD funded research are scientific or technical work products that must go through the clearance process prior to their release.

The Contractor shall coordinate their actions and the timing of the public meeting with representatives of Region 5 and the State of Ohio.

2. Measure the Mn content of hair samples and report the results to the EPA. As part of Contract EP-11-D-000424, the Contractor analyzed toenail samples collected during the November 2011 study in East Liverpool for Mn content. The Contractor shall use the same or an equivalent method to analyze all of the hair samples collected during this study. The Contractor shall ensure that any changes in the sample preparation, analysis, or data handling procedures do not affect the ability to make comparisons between the toenail and hair datasets.

3. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 1). The EPA anticipates that the article will be 20 typeset pages (including figures and references). Short Communications (of less than 1,000 words) and Meeting Proceedings papers (of less than 5 pages) will not be considered as acceptable to meet this requirement. The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt. The Contractor shall write a rough draft of the article based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.

In Option Year One, the Contractor shall perform the following Tasks:

4. Incorporate any EPA comments to the draft of Manuscript 1. The EPA will clear the article through the EPA Clearance Process within 21 calendar days of receipt (due to the requirements described above). After the article has been cleared, the Contractor shall submit the article to the specified Journal.
5. Incorporate journal reviewer comments and submit the final Manuscript 1 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
6. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 2). The EPA anticipates that the article will be 20 typeset pages (including figures and references). Short Communications (of less than 1,000 words) and Meeting Proceedings papers (of less than 5 pages) will not be considered as acceptable to meet this requirement. The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt. The Contractor shall write a rough draft of the article based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
7. Incorporate any EPA comments to the draft of Manuscript 2. The EPA will clear the article through the EPA Clearance Process within 21 calendar days of receipt (due to the requirements described above). After the article has been cleared, the Contractor shall submit the article to the specified Journal.
8. Incorporate journal reviewer comments and submit the final Manuscript 2 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
9. Prepare an outline of a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 3). The EPA anticipates that the article will be 20 typeset pages (including figures and references). Short Communications (of less than 1,000 words) and Meeting Proceedings papers (of less than 5 pages) will not be considered as acceptable to meet this requirement. The Contractor shall prepare an outline of the article with suggested conclusions and

the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt.

10. Prepare a journal article suitable for submission to a peer-reviewed journal which specializes in topic areas such as environmental health, epidemiology, clinical results, or exposure assessment (hereafter referred to as Manuscript 4). The EPA anticipates that the article will be 20 typeset pages (including figures and references). Short Communications (of less than 1,000 words) and Meeting Proceedings papers (of less than 5 pages) will not be considered as acceptable to meet this requirement. The Contractor shall prepare an outline of the article with suggested conclusions and the anticipated journal for submission for comment by the EPA. The EPA will provide comments on the outline and approval for the target journal within 21 days of receipt.

In Option Year Two, the Contractor shall perform the following Tasks:

11. Write a rough draft of the article, Manuscript 3, based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
12. Incorporate any EPA comments to the draft of Manuscript 3. The EPA will clear the article through the EPA Clearance Process within 21 calendar days of receipt (due to the requirements described above). After the article has been cleared, the Contractor shall submit the article to the specified Journal.
13. Incorporate journal reviewer comments and submit the final Manuscript 3 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
14. Write a rough draft of the article, Manuscript 4, based on the reviewed outline suitable for EPA and any other coauthor's review. The EPA will provide comments on the draft within 21 days of receipt.
15. Incorporate any EPA comments to the draft of Manuscript 4. The EPA will clear the article through the EPA Clearance Process within 21 calendar days of receipt (due to the requirements described above). After the article has been cleared, the Contractor shall submit the article to the specified Journal.
16. Incorporate journal reviewer comments and submit the final Manuscript 4 article to the journal for publication. The Contractor shall be responsible for all publication charges. The Contractor shall submit the final journal acceptance notice upon receipt.
17. Summarize the project descriptions, study protocols, study population demographics descriptions provided in the Study Plan that was submitted as part of Contract EP-11-D-000424 in a style suitable for an EPA Report. The Contractor shall summarize the analytical method sections, statistical method sections, and the study results sections of the Manuscripts developed during Contract EP-11-D-000424 and during this Contract in a style suitable for an EPA Report. The Contractor shall include all of the data from the East Liverpool, Ohio study; any data from other sources used in comparisons between communities; the results of data analyses; any statistical programming code; all data documentation and / or metadata as part of this summary package. The EPA anticipates that this summary will be based on previously supplied materials and will be no more than 75 pages in length. The EPA Report

style guide "Handbook for Preparing Office of Research and Development Reports, Third Edition" can be found on the EPA's National Service Center for Environmental Publications (NSCEP) website:
<http://www.epa.gov/nscep/index.html>

D. Government Responsibilities

The EPA will be responsible for annual renewals of the approval for the study from the EPA IRB of record, the University of North Carolina Institutional Review Board, and EPA Human Subjects Approval. The EPA will obtain clearance for the public meeting presentation package with 14 calendar days of receipt (due to the requirements described above). The EPA will provide comments on the outlines and manuscript drafts within 21 days of receipt. The EPA will clear the manuscripts through the EPA Clearance Process within 21 calendar days of receipt (due to the requirements described above).